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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,136

12/18/2006

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01/26/2009

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EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT

PAPER NUMBER

1634

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,136	<b>Applicant(s)</b> OLSON-MUNOZ ET AL.	
	<b>Examiner</b> Stephen Kapushoc	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 6-16 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-5 and 7-23 are cancelled. Claims 6-16 are pending and examined on the merits.

#### ***Election/Restrictions***

1. Applicant's election without traverse of the invention of Group 2, claims 6-16 in the reply filed on 10/17/2008 is acknowledged. The claims of the non-elected inventions (i.e. claims 1-5 and 7-23) have been cancelled.

#### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The Oath indicates that the specification of the instant application was filed on 01/10/2006, where USPTO records indicate that the instant application has a filing date of 12/18/2006.

The Oath indicates that PCT US/2004/022014 was filed on 7/10/2004, where records indicated that the PCT was filed on 7/09/2004.

#### ***Claim Objections***

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3. Claim 16 objected to because of the following informalities: Claim 16 recites the symbol '<', where the phrase 'less than' is appropriate. Appropriate correction is required.

***Claim Rejections - 35 USC § 112 2<sup>nd</sup> ¶ - Indefiniteness***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-16 are unclear over recitation of the intended purpose of the claimed method as 'a method for detecting aneuploidy of a chromosome', as recited in independent claims 6 and 9. The method require only the method steps of selecting an exon tag, providing a detection assay, and detecting the exon tag, where the method step do not in themselves detect aneuploidy of a chromosome. As such there is not a nexus between the recited purpose of the method and the method steps of the claimed method, and it is unclear how the method steps accomplish the stated purpose of the method.

Claims 12 and 13 are unclear over recitation of the phrases 'on chromosome 1' (as recited in claim 12) and 'the group consisting of chromosomes 13, 18, 21, X, and Y' (as recited in claim 13). The claims appear to require the analysis of particular nucleic acid molecules, but do not specific any species from which the require chromosomes,

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identified only by a number or letter designation, are obtained. The claim may be made more clear if amended to indicate, for example, 'on human chromosome 1' and 'the group consisting of human chromosomes 13, 18, 21, X, and Y', with an indication that the subject of the claimed method is a human subject.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 6, 8, 9, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Jalal et al (1998).

Regarding the limitations of independent claims 6 and 9, Jalal et al teaches a method for detecting aneuploidy of a chromosome in a subject. Jalal et al teaches selecting for analysis particular loci in particular chromosomes (e.g. p.132 - Materials and Methods), where the loci (e.g. 21q22.13-q22.2) encompass exon tag sequences as defined in the instant specification, relevant to step (a) of claims 6 and 9. Relevant to steps (b) and (c) of claims 6 and 9, Jalal et al teaches analysis using fluorescence in situ hybridization (FISH), which is a non-amplifying oligonucleotide detection assay (claim 6) and a non-amplified oligonucleotide detection assay (claim 7), to detect loci (Fig 1).

Regarding claims 8 and 11, Jalal et al teaches the simultaneous analysis of multiple chromosomal loci using the FISH method (Fig 1), which is providing and detecting an internal control.

Relevant to claim 13, Jalal et al teaches analyses including chromosomes 13, 18, 21, X and Y (p.132 – Materials and Methods).

Relevant to claim 14, Jalal et al teaches analysis of amniocyte cells and amniocyte cell culture samples (Fig 1).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jalal et al (1998) in view of Rogan et al (2001).

Jalal et al teaches a method for detecting aneuploidy in a subject comprising all of the limitations of claims 6 and 9, from which rejected claims 7, 10, and 12 depend.

Jalal et al does not provide for the particular methods of exon tag selection of claims 7 and 10, or an internal control comprising a sequence from a gene of chromosome 1. However, the use of such methods in the analysis of chromosome copy number were well known in the art at the time the invention was made.

Rogan et al teaches methods for chromosome analysis comprising generation of single copy probes. Relevant to claims 7 and 10, Rogan et al teaches methods of probe selection (p.1092 – Identification of single-copy sequences) comprising identification of single copy sequences, which are sequences that are chromosome specific and unique in the genome (relevant to step (a) of claims 7 and 10), and sequence comparisons to determine that probes are unique (e.g.: p.1092, left col., Ins.11-26; Fig 4). Rogan further teaches that probes comprise exon sequences (p.1087 – Sequence analysis of scFISH probes). Relevant to the limitations of claim 12, Rogan et al teaches probes for the detection of loci in chromosome 1 (Fig 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have performed the analysis of Jalal et al using probes designed by the methods of Rogan et al, including an internal control probe for the

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analysis of chromosome 1. One would have been motivated to use the methods of Rogan et al because Rogan et al teaches that such methods streamline the development of probes for chromosome analysis (p.1086). One would have been motivated to use a chromosome 1 probe for an internal control based on the teachings of Rogan et al that a probe to a locus of chromosome 1 can effectively detect copy number of the locus.

12. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jalal et al (1998) in view of Winsor et al (2001).

Jalal et al teaches a method for detecting aneuploidy in a subject comprising all of the limitations of claims 6 and 9, from which rejected claims 15 and 16 depend.

Jalal et al does not specifically teach that maternal nucleic acid is a contaminant in the amniocyte cells and amniocyte cell culture samples.

However, the presence of maternal nucleic acid in amniocyte cells and amniocyte cell culture samples was well known in the art at the time the invention was made and this property of such samples is taught by Winsor et al. Winsor et al teaches that maternal cell contamination in amniotic fluid was 21.4 % and 0.2 % in cultured fluid (p.49 – Abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have performed the analysis of Jalal et al on multiple amniocyte cell samples, where Winsor et al teaches that a property of such samples is the content of maternal cells comprising maternal nucleic acids.



### ***Conclusion***

**13. No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/  
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